MEDICAL SUCTION UNIT

OB2012 FA

USER MANUAL

CE 0123

MANUFACTURED BY:

BOSCAROL®
Emergency Medical Systems

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SYMBOLS

Disposable part

Applied part type BF

Double insulation

Read the user manual

Follow the instructions for use

Minimum and maximum temperature use

023555

The device conforms to the requirements of Directive 72/245/EEC

CE mark perform to the MDD 93/42/EEC for Medical devices with class above I

The device contains electrical and/or electronic equipment that must be recycled per EC Directive 2002/96/EC – Waste Electrical and Electronic Equipment (WEEE)

IMPORTANT SAFEGUARDS

When using electrical products, basic safety precautions should always be followed. Read all instructions before using.

Important information is highlighted by these terms:

WARNING important safety information to avoid the risk of injury to the user or patient and / or damage to the device

NOTE information to which you should pay special attention

WARNINGS AND PRECAUTIONS: READ CAREFULLY!

- Read carefully these instructions before using the device. Careful and proper use of the device ensures smooth operation and protection of patients and users.
- The OB2012 Suction Unit is an independent active medical device. The device is to be used to remove fluids from the airway or respiratory support system in medical procedures. For this reason its use should be undertaken by appropriately trained personnel.
- Never use the device to the presence of liquids, gases and flammable mixtures and / or explosives that could cause an explosion or fire.
- The use of the device in environmental conditions different from those in the manual may seriously compromise the safety and technical parameters of the device.
- In instances where suction takes place when the jar or protection filter are incorrectly installed or any foreign substances penetrate the unit, it's necessary contact the nearest service center.
- Before cleaning the unit or proceeding with any maintenance, disconnect the unit from the external power source. Do not submerge the unit in water.
- There are no user-serviceable parts inside the unit. The only operations allowed are those listed in this manual. For any technical problem for the periodic review and repairs please contact your authorized service.
- Use only genuine and authorised spare parts supplied by the manufacturer (Oscar Boscarol Company) or their agents. Using genuine spare parts will increase the reliability of the unit and ensure that the guarantee remains unaffected.
- Do not modify any mechanical or electrical parts on the wall-bracket. The replacement of parts of wall bracket and / or alteration thereof can seriously affect the safety anchorage of device.
- The device cannot be used to assist patients during investigations through NMR (nuclear magnetic resonance).

BATTERY

- Upon receipt of the device it's necessary to recharge it for at least 24 consecutive hours.
- Keep the device under load even when not in using. The persistent connection to the vehicle voltage (12 ÷ 15 VDC) does not damage the device, but allows maximum autonomy of the battery.
- Failure to regularly recharge the battery will lead to a 'deep discharge' at which time the battery will need to be replaced.

WARNING ON REUSE OF DISPOSABLE PARTS

- Reuse of disposable materials or parts may compromise the functionality of the device and represent direct and indirect sources of contamination for users and patients.
- Sterilization and / or cleaning of disposable parts (antibacterial filters, suction tubes, Jankauer, etc.) can cause structural degradation of the material and consequent dangers arising from loss of mechanical integrity.

IMPORTANT INFORMATION

Note:

The device was designed and tested according to the latest regulatory standards. The electrical connection of the device to non-compliant electrical systems and / or otherwise not performed by professional installer can damage device and also the electrical system. Please always consult a qualified staff with knowledge of the latest provisions!

Preventive maintenance and safety inspection:

The device should be checked at least once every 12 months from the authorized service center. Every 24 months an inspection of safety and technical maintenance is required instead. Refer to authorized service centers for planning of inspection. The periodic safety inspection of the device does not fall under warranty.

Contamination of the device:

It is strictly forbidden to send contaminated devices to the manufacturer, installer or service centres. Each device in these conditions will be refused and health authorities will be informed about possible contamination.

OB2012 Suction Unit

Inspect the vacuum cleaner and all of its parts before using.

Do not use the device if it has damaged or missing parts.

Model BSU150:

1. Suction unit
2. OB-J FA jar
3. Protection filter
4. Conical connector
5. Silicone tube for filter connection
6. Charging cable
7. Jankauer suction tube

NOTE

For other models refer to the catalog available at www.boscarol.it .

Description and intended use statement

The OB2012 FA is a portable, battery operated medical suction unit, used for remove fluids from the upper airway and restore breathing either spontaneously or with assistance. High vacuum values are normally used for the suction of oropharyngeal tract, whereas low values are used for tracheal suction of children or newborns. The device can be used in emergency health services, in first aid, medical services in private homes and hospitals fixed or mobile. The device is complete with storage bag.

Contra indication for use

Do not use the OB2012 for draining the thorax.

Controls, indications and check panel

All the controls of the suction unit are on the front. The unit can be controlled when fitted on the wall-bracket or in the carrying bag.
To activate the device, press the switch (4), which is protected against the ingress of humidity, water and other fluids. The vacuum adjustment is possible by turning the knob (5) placed over switch. Turning the control knob clockwise will increase the vacuum. The monitoring of required vacuum is possible by the analog vacuum meter (1) and is expressed in millibars (mbar) and kilo-pascal (kPa) or millimeters of mercury (mmHg).
On the back are two contacts (7) that allow the charging of the device if fitted on the wall bracket. Alternatively, you can use the charging cable plugged into the external 3-pin connector (6) on the side of device.

Fig.1

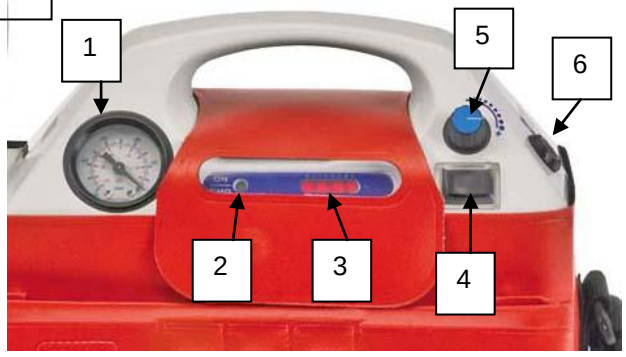
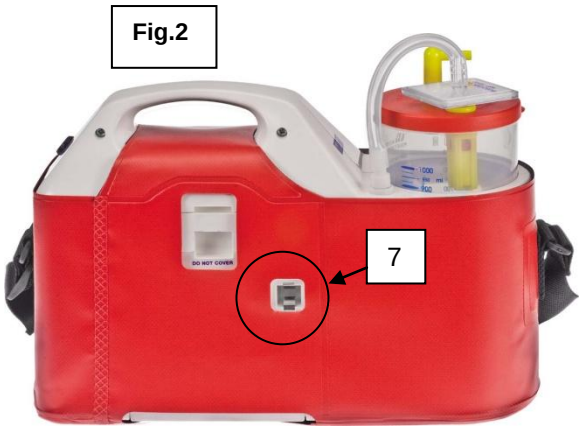


Fig.2



Indicator lights

All lights are placed on the front and display the operation of the device (see Fig1) : the autonomy of the battery (3) and the recharge state (1). The table below indicates the condition of the LEDs and the relative power of the battery:

LEDS STATUS	BATTERY POWER LEVEL
4 LEDS on	>80% maximum power
3 LEDS on	50-75% of the maximum power
2 LEDS on	20-40% of the maximum power
1 LED on	**<20% low battery voltage – recharge immediately**

The indicator for charging <ON/CHG> (2), placed next to the indicators of autonomy, has two different colors: ***Red indicates that charging is taking place***; ***green indicates that charging is complete.*** The indicator lights up whenever the device is connected for recharging. If the LED does not light up, there could be a malfunction of internal recharge circuit, lack of power (12 Vdc) or lack of connection of external cable to a power source for 12 Vdc.

WARNING

Always check the right connection of the cigarette lighter: the vibration of vehicles might cause its release. The continuous charging of the device does not damage the internal battery and can always enjoy maximum autonomy. It's always necessary to recharge the battery after each use. The use of the device when the battery is discharged will destroy the internal battery.

Daily checklist

The operations described in this section allow the user to verify the correct functioning of the suction unit. The test should be performed at least once a day and before use in the field:

- Disconnect the unit from the wall bracket or from the external charging cable;
- place the unit on a stable surface in the upright position (e.g. on a table);
- switch the unit on;
- check the indicator lights for battery power (when the battery is fully charged, all of the lights will be on);
- turn the regulator knob clockwise to maximum;
- cover the patient tube (on the collection jar) with a finger or a lint free cloth;
- check the maximum value of the vacuum (-800 mbar +/-10%) on the gauge;
- turn the regulator knob anti-clockwise and check the reading on the gauge.

When finished, compare the results of this test with the value on the table below:

Test – phase	Result	Remedy
Switch the unit on.	The indicator lights for the power and the pump motor switch are on (noise from the motor).	Pump failure and/or battery completely discharged. Recharge the battery and check the indicator light goes green.
Check the battery power.	When the battery is fully charged all red lights will be on.	Recharge the unit immediately.
Check the maximum vacuum.	Value range between 700 and 800 mbar (70 kPa ÷ 80 kPa; 525 ÷ 600 mmHg).	Check that the lid on the collection jar is tight and that all connections are secure. Change the disposable liner.
Check the vacuum regulation.	Gauge reading ranges from maximum to minimum.	Check the vacuum connections and/or the regulator (anti-clockwise for minimum vacuum).

WARNING

In the event of continued problems after taking the action outlined above, send the unit to an authorised service centre for service or repair.

OB-J FA collection jar

The device is sold with a reusable jar OB-J FA (Fig. 3). The jar is made of transparent plastic material (polyprophilen). It includes pot (1), cover (2), the shut-off valve (3) and the 90° plastic pipe (4). The lid of the jar provides the direct inclusion of the protection filter.
The jar can be sterilized in an autoclave (max. pressure 2 bar(g) and maximum temperature 121°C) for a maximum of 15 minutes. **It is strongly recommended that the collection jar is replaced after 30 autoclave cycles.** The jar must always be used in the upright position, to avoid the intervention of shut-off valve. Should this occur, switch the device off and disconnect the patient tube ('VACUUM' marked on the lid).

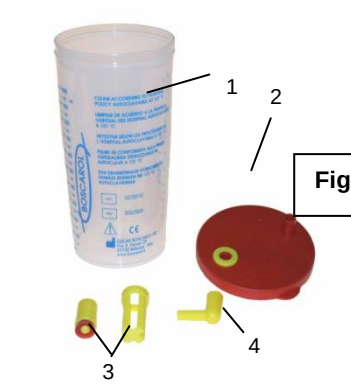


Fig.3

Protection filter

To prevent fluid overflow, a special protection filter is used between the jar and the unit. The filter is produced with PTFE hydrophobic material which prevents fluids entering the pneumatic circuit. Working together with the shut-off valve on the jar, the filter isolates the pneumatic suction pump from gas and fluid substances. Replace the filter when you look at contamination, discoloration or increased resistance of aspiration.

Warnings and precautions on the use of protection filter

If the suction unit is used either in an emergency or on a patient where the risk of contamination is not known, the filter must be changed after each use.
If instead the patient's pathology is known and / or where there is no danger of cross contamination, we recommend replacing the filter after each shift. In case of complete inactivity of the unit is recommended to replace the filter once a month. The material it is made should be damaged even under specific environmental conditions (humidity, heat, cold)

Do not use the suction unit without the protection filter or jar!!

Jankauer suction tube and Finger-typ end-piece

The suction unit is sold complete with a sterile, Jankauer type suction probe which is connected to a plastic suction tube. **The probe and the tube are disposable and must be changed after each use.** To facilitate correct operation, the probe is angled to allow ease of entrance to the mouth and the respiratory airway.

A different type of suction set, which includes a silicone tube (length 130cm – 51.2in) and one Finger-tip sterile joint, is available at customer request. Finger-typ joint allows the user to control the vacuum by opening or closing a venturi hole with a finger. When the venturi hole is completely open, the vacuum will operate at the minimum value, with the venturi hole completely closed the vacuum will operate at the value set on the unit. Silicone tube is sterilizable, Finger-typ is disposable.

Power supply and charging of the battery

The unit is equipped with an internal rechargeable battery (non user-replaceable). The maximum time for charging the battery (as the residual capacity) is about 15 hours. The times fall significantly if the device is recharged after each use.
A fully charged battery will provide approximately 45-60 minutes of continuous operation at zero vacuum level (free flow).
It is considered an average life of the battery, if properly loaded, equal to 24 months.
In case of inactivity for a long time, run every 15 days a complete control and charging for at least 24 consecutive hours.

The device can be recharged via the supplied cable, the wall bracket or the battery charger power supply (100÷230 Vac). The charging cable must be connected to a power source between 12 and 15 Vdc. To allow the use and recharge, the device must be connected to an external power source (12÷15 Vdc) that can provide at least 6A.

Charging cable
BSU854

OB20WB wall bracket
BSU800

Battery charger
BSU870 (EU) – BSU872 (UK) – BSU874 (JP)

WARNING
Check that the external power source is correctly rated. The external power source has to be protected by a security fuse with a minimum rating of T15A (delayed type).

The battery charger is an exclusive accessory, available only from the manufacturer. It can only be used indoors.

WARNING

Do not use the suction unit on a patient with the battery charger connected to the mains electricity supply. The mains voltage can be deadly to humans!

Checking the battery

To verify and monitor the autonomy of battery and / or in case of suspicion of revocation of the same, do the following:

- Charge the device for at least 15 consecutive hours;
- set the maximum value of vacuum closing the vacuum regulator (clockwise);
- let the unit run without closing the patient tube for at least 20 consecutive minutes;
- if the unit stops working earlier than 20 minutes, the battery is damaged and must be replaced.

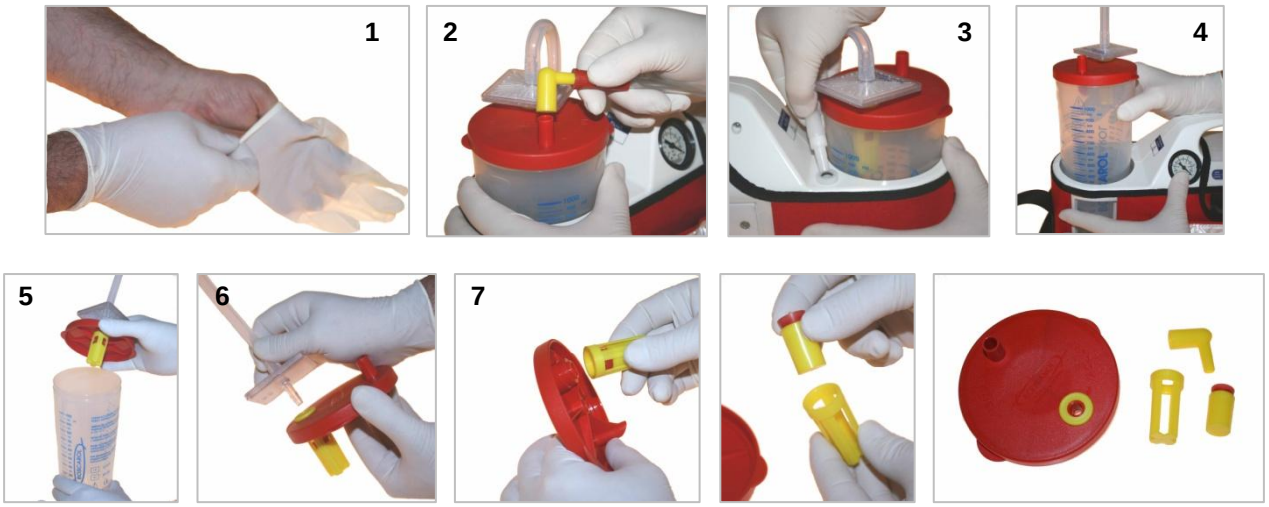
MAINTENANCE AND REUSE

After each reuse

After each use, disconnect the unit from external power source, disconnect the single patient use - disposable parts (e.g. Finger-tip, catheters, liner etc.) and dispose of them according to local regulations. Verify the integrity of the device, check the connecting tubes and structural abnormalities. Clean and disinfect the unit as described below. Replace all single use - disposable parts with new components and recharge the battery.
Make a daily function test as described under "Daily checklist" on page 7.

CLEANING INSTRUCTION

Reusable collection jar OB-J FA



1. Wear gloves and protective clothing.
2. Disconnect patient tube.
3. Disconnect silicone tube and conical connector.
4. Carefully remove the jar from the unit.
5. Remove the lid of the bottle (attention to possible contamination with the liquids contents!). Empty the contents of the bottle in accordance with local regulations or hospital practice.
6. Disconnect the protection filter.
7. Disassemble the shut-off valve.

Dispose of disposable parts and disassembled the jar, soak the parts in cold water and rinse well. Then dip the same parts in hot water at a temperature not exceeding 60 ° C containing a mild, non-alcoholic detergent. After washing, rinse

all parts with clean hot water (30-40°C max.) and then dry with a lint free soft cloth. Before reassembling, check that all parts are clean, dry and undamaged.

Decontamination of the collection jar

The collection jar can be disinfected with any mild, non-abrasive detergent. Do not use any alcohol or solvent-based cleaning agents as these may damage the collection jar. Do not use coloured disinfectant solutions as these may stain the collection jar. Never use neat disinfectant dilute according to the manufacturer's instructions. The jar is manufactured from plastic and, whilst it offers good protection against water and humidity, long periods of immersion in water or detergents may affect its integrity. For sterilisation, only use steam autoclaves at a maximum temperature of 121°C at a maximum pressure of 2 bar(g) for 15 minutes. The jar should be placed in the autoclave upside-down to assist draining. At the end of the autoclave cycle, place all parts on a flat, sterile (or clean) surface and leave to cool to ambient temperature before reassembling. Check that the collection jar and all parts are undamaged.

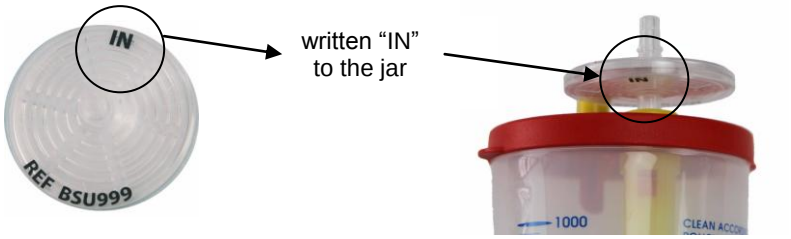
WARNING

- **Do not put weight on the parts during the sterilisation cycle.**
- **Observe the maximum limits for temperature, pressure and duration during the autoclave cycle.**
- **Never exceed the value of 60°C for washing or cleaning operations (with the exception of sterilization in a steam autoclave).**
- **Cleaning, disinfection and sterilisation should only be carried out by trained personnel.**
- **The collection jar can be used for up to 30 sterilisation cycles, after which, the jar, tubes and plastic connectors must be replaced.**
- **After reassembling the jar, check that the lid is properly fitted to achieve a seal.**

Place all components on a flat, clean surface. During the assembly phases, check all parts for damage. Ensure that the shut-off valve moves freely inside its cage. To remove the filter, pull gently and twist holding the outer rim of the filter whilst supporting the collection jar by the lid. Take care not to damage the filter.

Replacing the protection filter

Disconnect the tube from the top side of the contaminated filter. Carefully remove the filter from the collection jar lid and dispose of it in accordance with local regulations or hospital practices. Install a new filter ensuring that the written "IN" is on the underside, above the 'VACUUM' port on the lid. Incorrect installation of the filter will lead to immediate failure when used.



NOTE

Ensure that the protection filter is correctly fitted to the collection jar (with written "IN" to the jar). The filter may break if fitted incorrectly and there is a risk of unit contamination.

Disposal of contaminated parts

Always follow local regulations or hospital practices when dealing with contaminated materials. Never store contaminated parts with new or sterile parts.

Cleaning the suction unit

To clean the chassis of the suction unit, use a damp cloth with mild detergent. Rinse the chassis with a damp cloth and dry it with a soft towel.

WARNING

- **Before cleaning the suction unit, ensure that all external power supplies have been disconnected.**
- **Never immerse the suction unit in water.**
- **Do not use abrasive substances, alcohol or solvents to clean the chassis.**

In order to correctly disinfect and decontaminate the device, we suggest you to use specific products, not harmful for people and the environment. These disinfectants must be free of alcoholic and abrasive substances.
Oscar Boscarol srl can provide you of specific equipment for disinfection of medical equipment, including the suction units we produce.

DISINFECTANT'S CODES

- **MED99050** Kit spray for disinfection of medical devices
- **MED99051** Concentrate for disinfection of medical devices 5 lt
- **MED99052** Disinfectant wipes – pack of 200 pcs
- **MED99055** Disinfectant wipes in sachets – pack of 200 pcs
- **MED99060** Bactericidal disinfectant spray 500 ml
- **MED99100** DRY MIST device for environmental disinfection
- **MED99101** Active solution for DRY MIST 500 ml

These disinfectants are tested in laboratory and guarantee the deactivation of viruses, bacteria and microorganisms. Periodically used, they prevent and destroy the formation of dangerous bio-films (superficial layers that easily host bacteria, molds, viruses and microorganisms). The disinfectants we commercialize do not contain alchol, chlorine, phenols, aldehyde and halogens.

Safety

On the back of the unit is placed a 15A fuse (delayed type function T), which protects the battery circuit and the suction pump. In the event that it activates, replace it (spare fuse delivered with the suction unit or requested from the manufacturer). Use a flat head screwdriver to unscrew the head holder. Replace the fuse with a new one and screw the head into place. If after replacing of the fuse the device does not work, contact the service center.

Disposing of the suction unit

The unit contains electrical and/or electronic equipment that must be recycled per EC Directive 2002/96/EC – Waste Electrical and Electronic Equipment (WEEE).

ACCESSORIES AND SPARE PARTS

Index code	Description
	Accessories
BSU800	OB20WB wall bracket
BSU870	Battery charger 100/240 Vca 50/60 Hz - 3 poles and Euro-plug
BSU872	Battery charger 100/240 Vca 50/60 Hz - 3 poles and UK-plug
BSU874	Battery charger 100/240 Vca 50/60 Hz - 3 poles and Japan / USA-plug
	User parts
BSU730	Protection filter for OB-J FA jar – 5 pcs
BSU732	Protection filter for OB-J FA jar – 15 pcs
BSU734	Protection filter for OB-J FA jar – 40 pcs
BSU500	Autoclavable OB-J FA jar, without protection filter
BSU776	Jankauer suction tube
BSU750	End-piece sterile disposable Finger-typ – 5 pcs
BSU752	End-piece sterile disposable Finger-typ – 15 pcs
BSU754	End-piece sterile disposable Finger-typ – 50 pcs
11214101003	Sterile suction catheter Ch.10 black
11214101104	Sterile suction catheter Ch.12 white
11214101005	Sterile suction catheter Ch.14 green
11214101006	Sterile suction catheter Ch.16 orange
11214101007	Sterile suction catheter Ch.18 red
11214101008	Sterile suction catheter Ch.20 yellow
	Spare parts
BSU854	External charging cable with cigar lighter fitting and 3 poles plug
BSU902	Silicone patient tube - length 130cm / 51,2inch (int.diam.6mm/ext.12mm)
SPS6000	Bottle OB-J FA without lid
SPS6002	Shut-off valve – 3 pcs
SPS6004	90° plastic joint for OB-J FA jar – 3 pcs
SPS6006	Lid for OB-J FA complete with shut-off valve and 90° plastic joint
SPS6014	Conical connector – 5 pcs
SPS6023	Silicone tube 15 cm with conical connector for OB-J FA
BSU834	Red carrying bag
ZMA3000	User manual

NOTE

The parts listed in the list may be changed without prior notice from the manufacturer and / or technical improvements. Contact the manufacturer for more information**.**

SERVICE

There are no serviceable components inside the suction unit**.** Do not open the suction unit and do not modify any electrical or mechanical parts. Always contact your service center or the manufacturer. Any even minimal intervention on the device voids the warranty. Unauthorized intervention may compromise its conformity with the applicable laws and reduce the security to the detriment of users and patients.

FAULT FINDING

Malfunction	Possible cause(s)	Corrective action
The suction unit doesn't work when powered by the internal battery.	• Completely discharged battery. • Faulty battery.	• Charge the unit for at least 24 hours. • Refer to authorised service personnel.
The suction unit doesn't work when mounted on the wall bracket or with the external charger cable.	• Cable damaged. • Damaged wall bracket and/or contacts on the suction unit. • External power source failure (12÷15 Vdc - min.6A).	• Replace the cable. • Replace the wall-bracket. • Check the external power source.
The suction unit only works if it is mounted on the wall-bracket or fitted with the external cable.	• Fuses blown. • Faulty battery.	• Replace the fuse (see page 12). • Refer to authorised service personnel.
The battery charger doesn't work properly.	• Faulty battery charger.	• Check the Charging LED. If it is on, but the battery is not charged, please refer to authorised service personnel. • Replace the battery charger.
The suction unit works, but the battery power indicator lights are off.	• Faulty internal circuit. • Very low battery power.	• Check that the indicator lights work if connected to the wall-bracket or to the external charger cable. If they work, immediately charge the battery for at least 24 hours. • Charge the battery for at least 24 hours.
The suction unit only works for a short time.	• Faulty battery. • Internal recharging circuit failure.	• Test the suction unit as described in page 10 of this manual or refer to authorised service personnel. • Refer to authorised service personnel.
The vacuum power on the patient side is either very low or absent.	• Vacuum regulator set to minimum. • Protection filter blocked or damaged. • Connection tubes blocked, kinked or disconnected. • Shut-off valve blocked or damaged. • Pump motor damaged.	• Turn the vacuum regulator clockwise and check the value of the vacuum on the gauge. • Replace the filter. • Replace or reconnect the tubes, check the jar connections. • Replace the reusable jar. • Empty the jar, or disconnect the tube from the jar and unblock the shut-off valve. The unit will only work in the upright position. • Refer to authorised service personnel.
Vacuum is always at maximum even if the jar is removed.	• Fault on the internal pneumatic circuit.	• Refer to authorised service personnel.
High noise, low suction, high vibration.	• Internal pump damaged.	• Refer to authorised service personnel.

TECHNICAL DATA AND CONFORMITY TO INTERNATIONAL LAW

Classification according to the MDD93/42/EEC

The OB2012 suction unit is an ACTIVE MEDICAL SUCTION UNIT for use in the field and for transportable use in accordance with ISO10079-1:2009.

MDD Classification:	**IIb**
Vacuum degree:	HIGH VACUUM-HIGH FLOW
Mode of operation:	TEMPORARY (maximum continuous use 60 minutes)
Electrical requirements:	SELV (12÷15 Vdc)
Use of the device in the home environment:	complying to IEC60601-1-11:2010
Degree of protection against electric shock (IEC60601-1):	TYPE BF
With respect to protection from electric shock:	CLASS II
Degree of protection against ingress of liquids (IEC529):	IP34d
Accordance with general IEC60601-1:	Complying with the 3° Edition

Dimensions

Max dimensions:	350 mm (width) x 120 mm (depth) x 240 mm (height) 13.77 in (width) x 4.72 in (depth) x 9.44 in (height)
Weight:	4.6Kg max. complete with all accessories
Tolerance on all values:	±5%

Technical data

Max vacuum power:	800 mbar (80 kPa, 600 mmHg) ±10%
Vacuum Regulation:	linear
Vacuum range regulation:	30÷800 mbar (3÷80 kPa; 225÷600 mmHg)
Max flow rate:	30 litres per minute with free air ±10%
Max running time with the maximum current-load:	Approximately 40 minutes ±10%
Approximate maximum noise energy:	70 dBA
Accuracy of the analogue gauge:	±5%
Accuracy of the battery power monitor:	±5%

Power supply

Running/charging:	12÷15 Vdc (Direct Current)
Max current load:	70 W (max. current 6 A)
Battery:	Internally mounted, rechargeable hermetically sealed acid type, Capacity 4 Ah
Max time for recharging:	15 hours
Main safety:	T15A (user replaceable)

NOTE

The external power source must supply at least 6A to allow correct running or charging of the unit. With the mains powered battery charger, when the unit is running, the power is drawn from the battery.

Environmental and transport conditions

Operating temperature range:	0÷50 °C (32÷122 °F)
Recommended temperature for charging	15÷30 °C (59÷86 °F)
Storage and transport temperature range (with original packaging):	-25÷55 °C (-77÷131 °F)
Storage and transport temperature range (without packaging):	0÷50 °C
Storage, use and transport relative humidity:	15÷95%, not condensed
Storage and transport atmospheric pressure:	70÷106 kPa (700÷1060 mbar; 525÷795 mmHg)

NOTE

Be aware that if the unit is operating at an altitude over 2,500 meters, the pressure value can slightly decrease. This is caused by the decrease in the atmospheric pressure.

Operating in the rain

Although the OB2012 FA is protected against water drip, it should never be used in very heavy rain. During either operation or storage, the unit must always stand upright. In the event that water gets into the side compartments, remove the suction unit and dry thoroughly.

Protection filter technical data

Antibacterial / viral filter for suction devices, with PTFE filter and polypropylene hermetically sealed chassis.

Max pressure applicable: 1bar (100kPa)
Retention capacity:

- for water solution: up to 0,9bar (90kPa)
- nebulized parts: 0,1um 99,99%

Battery chargers technical data

Input: 100÷240 Vac 50/60Hz, 600mA
Output: 24 Vcc 1 A max

Symbology

Vac =	Voltage (alternating current)
Vdc =	Voltage (direct current)
°C	degrees °C
bar	unit for pressure and vacuum
kPa	unit for pressure and vacuum
mmHg	unit for pressure
Conversion formula:	1bar = 100kPa = 750mmHg

THE RISKS OF RECIPROCAL INTERFERENCE WITH OTHER DEVICES

The OB2012 suction unit does not create interferences with other medical devices that are operating in the same area during the conduct of investigations and clinical treatments. The unit must not be connected to other equipment for its operation and has an internal power source.

RISK OF ELECTROMAGNETIC INTERFERENCE AND POSSIBLE REMEDIES

The electro medical units required special precautions of use with regard to electromagnetic compatibility. For this reason must be installed and/or used in accordance with the information specified in the accompanying documents (in our case the following tables).
Portable radio devices and mobile may affect the functioning of the medical device.
The electro medical units and medical systems should not be used in proximity, adjacent or overlapping with other electrical apparatus or radio. If such use is necessary and unavoidable, special precautions must be taken to ensure that the medical device is functioning properly in its configuration of use envisaged (for example, checking constantly and visually the absence of anomalies or failures). The following tables provide information about the features of EMC (electromagnetic compatibility) of this electro medical unit. The full functionality of this unit is considered "essential services" for the purposes of electromagnetic immunity.

POSSIBLE METHODS TO AVOID THE RISKS OF ELECTROMAGNETIC INTERFERENCE

In the case that medical unit can influence or be influenced by other electrical appliances places nearby, try to change the place of use, remove sources that emit radio frequency (cell phones, two-way radios, mobile antennas). Try to move away from where you are (if possible) or turn off all non-essential appliances nearby places (including the electro-domestics) and follow the directions below.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

The OB2012 suction unit is intended for use in the electromagnetic environment specified below. The customer or the user of the OB2012 suction unit should assure that it is used in such an environment.

Emissions tests	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The OB2012 suction unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The OB2012 suction unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	

Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The OB2012 suction unit is intended for use in the electromagnetic environment specified below. The user of the OB2012 suction unit should assure that it's used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV in air	±6 kV contact ±8 kV in air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2 kV power supply ±1 kV power supply (IN/OUT)	±2 kV power supply ±1 kV power supply (IN/OUT)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5%U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5%U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the suction unit OB2012 requires continued operation during power mains interruptions, it is recommended that the suction unit be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	0,3 A/m	If abnormal performance is observed on the suction unit OB2012, it may be necessary to position the suction unit OB2012 further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

NOTE: U_T is the AC mains voltage prior to application of the test level.

GUIDELINES AND DECLARATION OF COMPLIANCE FOR MEDICAL DEVICES

TEST OF CONDUCTED AND RADIATED ELECTROMAGNETIC IMMUNITY

For the purposes of conducting the tests using test levels IEC60601, **V_1=3 and E_1=10**

The BSU suction units are intended for use in the electromagnetic environment specified below. The user of the OB2012 suction unit should assure that it's used in such an electromagnetic environment.

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the OB2012 suction unit, including cables, than the recommended separation distance calculated from the equation applicable to frequency of the transmitter: Recommended separation distance d= 1,2√P d= [3,5/E1] x √P = 0,35√P da 80MHz a 800MHz d= [7/E1] x √P = 0,7√P da 800MHz a 2,5GHz where <P> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <d> is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ([a]), should be less than the compliance level in each frequency range ([b]). Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	10 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

([a]) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the suction unit OB2012 is used exceeds the applicable RF compliance level above, the suction unit OB2012 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the suction unit OB2012.
([b]) Over the frequency range 150 kHz to 80 MHz, field strength should be less than 1 V/m.

GUARANTEE

Oscar Boscarol Company supplies the OB2012 FA with a 36 month guarantee from the date of purchase. The company guarantees that each new OB2012 FA unit is free from defects in materials and workmanship.

Items excluded from this guarantee are: ***the collection jar and/or the liner, the external cable for battery charging, the internal battery, normal wear and tear of the unit, discoloration, and any other aesthetic irregularities which do not affect the operation of the unit.***

The product that during the 36 months warranty is found defective, should be sent to Oscar Boscarol srl with a note describing the defect. The Oscar Boscarol Company will, at their discretion, arrange for repairs or complete replacement within the terms of this guarantee. All shipping costs are borne by the customer.

Conditions of guarantee:

To use the warranty, it is necessary to fill in and return the product registration form below, via post, fax or mail, to the following address:

OSCAR BOSCAROL COMPANY V. E. Ferrari, 29 – 39100 BOLZANO - ITALY
Fax: +39 0257760142 – E-mail: production.manager@boscarol.it

To validate the guarantee, the customer shall provide the following documentation:

- presentation of a copy of the invoice and / or declaration of purchase containing the device serial number and date of purchase;
- recognition by the service of a failure or defect attributable to defects in materials or workmanship;
- absence of tampering, changes and / or anything not conforming to the original product.

Effects of safety, reliability and functioning of suction unit, Oscar Boscarol srl is liable only if:

- All technical operations, repairs, modifications and maintenance actions are carried out at the Oscar Boscarol company factory or by an authorised service centre.
- The device is used correctly, as indicated in this user manual.
- The suction unit charger is only to be connected to the correct voltage supply for the Country it was supplied.

With reference to what was described in these guarantee conditions, Oscar Boscarol Company cannot be responsible for accidental or indirect damage resulting from unauthorised modification or repair, unauthorised technical interventions or when any parts of the unit are damaged in instances of accidental or incorrect use. On the OB2012 suction unit are no other warranties expressed or limited, of merchantability, fitness or other outside those described in this manual.

DECLARATION OF CONFORMITY

We, the manufacturer: *Il produttore:*	**OSCAR BOSCAROL srl** Via E. Ferrari , 29 – 39100 BOLZANO – ITALY Tel. +39 0471 932893 – Fax. +39 0257760140 Web: www.boscarol.it - Email : info@boscarol.it Certifies EN ISO 13485:2012 Certificate N° Q1N 12 07 42208 019 Certifies UNI EN ISO 9001:2008 Emission: TÜV–SÜD Product service (CE0123) EC Certificate N° G2 13 01 42208 020 EC Certificate N° G1 13 01 42208 021 EC Certificate N° G1 13 01 42208 022 EC Certificate N° G1 13 01 42208 023
We declare under our sole responsibility that the device (name): *Dichiariamo sotto nostra responsabilità che il dispositivo (nome):*	**MEDICAL SUCTION UNIT** **ASPIRATORE MEDICALE DI SECRETI**
Type: **Tipo:**	**OB2012 FA – OB2012 LINER**
UMDNS code:	**15016**
Boscarol code:	**BSU100 - BSU102 - BSU104 - BSU106 - BSU108** **BSU110 - BSU150 - BSU152 - BSU154 - BSU156** **BSU158 - BSU160** **XAS0200 - XAS0210 - XAS0220 - XAS0230** **XAS0240 - XAS0250 - XAS0260 - XAS0300** **XAS0302 - XAS0304 – XAS0356 – XAS0400** **XAS0402**
Devices classification (MDD 93/42/EEC – Annex IX): *Classificazione dispositivo (MDD93/42/CEE – Allegato IX):*	**Class IIb**
Meets all the provisions of the directive MDD 93/42/EEC and subsequent amendments which apply to it. *Soddisfa tutte le disposizioni della direttiva MDD 93/42/CEE e successivi emendamenti che lo riguardano.*	
Applied harmonised standards, national standards or other normative documents: *Norme armonizzate o nazionali applicate, altri documenti normative applicate:*	**ISO10079-1:2009** **IEC60601-1 3rd Ed.** **e1 – DIR72/245-EEC** **EN1789:2010** **IEC60601-1-11:2010**
Conformity assessment procedure: *Procedimento di valutazione della conformità:*	**MDD93/42/EEC, Annex II (Allegato II)**
Notify body: *Organismo di notifica incaric. della valut. della conformità:*	**TÜV – SÜD Product Service GmbH** **CE 0123**

Bolzano, 02.03.2013

DI/RAQ – Quality Manager
PERINI LAURA

DI/GM – General Manager
BRAZZO DANIELE

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